

3587. Adulteration of Lobelia herb. U. S. v. 11 Bales * * *. (F. D. C. No. 30709. Sample No. 10773-L.)

LIBEL FILED: March 19, 1951, Southern District of Indiana.

ALLEGED SHIPMENT: On or about November 13, 1950, and January 5, 1951, by the Smoky Mountain Drug Co., from Bristol, Tenn.

PRODUCT: 11 bales, each containing from 81 to 183 pounds, of *Lobelia herb* at Tipton, Ind.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy substance by reason of the presence of insects, insect fragments, and rodent hair fragments.

DISPOSITION: June 5, 1951. The Smoky Mountain Drug Co., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for washing and pasteurizing, under the supervision of the Federal Security Agency. On June 20, 1951, the decree was amended to provide for release of the product for the purpose of extracting the alkaloids therefrom, in lieu of its release for washing and pasteurizing.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

3588. Adulteration and misbranding of conjugated estrogens. U. S. v. 1 Drum * * * (and 1 other seizure action). (F. D. C. No. 31317. Sample Nos. 10341-L, 10342-L.)

LIBELS FILED: July 3, 1951, Eastern District of Michigan.

ALLEGED SHIPMENT: On or about January 5 and 11, 1951, by Strong Cobb & Co., Inc., from Cleveland, Ohio.

PRODUCT: 1 drum containing 52,400 tablets and 1 drum containing 33,200 tablets of *conjugated estrogens* at Detroit, Mich.

Analysis showed that 1 drum of the product (0.625 mg. tablets) contained a total amount of estrogenic steroids calculated as 0.40 mg. of sodium estrone sulfate per tablet and that the other drum of the product (1.25 mg. tablets) contained a total amount of estrogenic steroids calculated as 0.68 mg. of sodium estrone sulfate per tablet.

LABEL, IN PART: (Drum) "Contents 52400 * * * Name: Conjugated Estrogenic Hormone Substance * * * (0.625 mg. activity)" and "Contents 33200 * * * Name: Conjugated Estrogenic Hormone Substance Tablets (1.25 mg. activity)."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the articles differed from that which they were represented to possess, namely, 0.625 mg. per tablet and 1.25 mg. per tablet, respectively, of estrogens in their naturally occurring water-soluble conjugated form expressed as sodium estrone sulfate.

Misbranding, Section 502 (a), the following statements on the labels of the articles were false and misleading as applied to products which contained less than the stated amounts of total estrogenic steroids calculated as sodium estrone sulfate: "Formula contains at time of manufacture per tablet Estrogens (naturally occurring water-soluble conjugated form) expressed as sodium estrone sulfate 0.625 mg. * * *" and "Formula contains at time of manufacture per tablet Estrogens (naturally occurring water-soluble conjugated form) expressed as sodium estrone sulfate 1.25 mg. * * *."

*See also No. 3584.

DISPOSITION: August 10, 1951. Strong Cobb & Co., Inc., claimant, having consented to the entry of decrees, judgments of condemnation were entered and the court ordered that the products be released under bond for reprocessing to bring them up to the required potency, under the supervision of the Federal Security Administrator.

3589. Adulteration and misbranding of oil of peppermint. U. S. v. 3 Bottles
* * *. (F. D. C. No. 31185. Sample Nos. 15265-L, 15353-L.)

LABEL FILED: On or about June 21, 1951, Western District of Missouri.

ALLEGED SHIPMENT: On or about May 8 and November 30, 1950, by Berje Chemical Products, Inc., from New York, N. Y.

PRODUCT: 3 bottles of *oil of peppermint* at Kansas City, Mo. Analysis of the product showed that it failed to comply with the requirements of the United States Pharmacopeia and that it also contained mineral oil.

LABEL, IN PART: (Bottle) "Oil Peppermint Redistilled U.S.P. 5 Lbs."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be "oil of peppermint," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from, and its quality and purity fell below, the official standard since the article failed to meet the tests for solubility in alcohol, specific gravity, and optical rotation; and it failed to comply with the assay for total menthol set forth in such compendium. Further adulteration, Section 501 (d) (2), an article containing mineral oil had been substituted for oil of peppermint.

Misbranding, Section 502 (a), the label designation "Oil Peppermint Redistilled U. S. P." was false and misleading as applied to an article which failed to meet the standard set forth in the United States Pharmacopeia for oil of peppermint.

DISPOSITION: August 31, 1951. Default decree of destruction.

3590. Adulteration and misbranding of clinical thermometers. U. S. v. 696 Thermometers * * *. (F. D. C. No. 31707. Sample No. 16776-L.)

LABEL FILED: September 17, 1951, Southern District of California.

ALLEGED SHIPMENT: On or about July 6, 1951, by the Emrose Thermometer Co., from Bronx, N. Y.

PRODUCT: 696 *clinical thermometers* at Ventura, Calif. Examination of 24 thermometers showed that a total of 8 were defective in one or more respects.

LABEL, IN PART: (Envelope) "Style Oral Emrose 'Medik-Aid' A Superior Clinical Thermometer."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the articles fell below that which they purported and were represented to possess.

Misbranding, Section 502 (a), the statements which appeared in the labeling of the articles, namely, "A Superior Clinical Thermometer," "This certifies that the thermometer * * * has been tested * * * at 98°, 102°, and 106°, F. or its equivalent in centigrade scale and is correct within plus or minus 2/10 F. or C. at any of these test points * * * This test is governed by a standard thermometer which has been tested by the Bureau of Standards, Washington, D. C.," and "Accurate," were false and misleading as applied to articles which failed to meet the stated standard of accuracy, contained trapped gas, failed to repeat readings, were hard shakers, or had markings less than